

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Suhaila White, *et al.*

Application No.: 10/732,894

Filed: December 10, 2003

For: Methods and Compositions for  
Modulating NF-AT Transcription Factor

Examiner: Tara L. Garvey, Ph.D.

Art Unit: 1636

Confirmation No.: 6903

**Response to Restriction Requirement**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

This is submitted in response to the Office Action dated August 9, 2006 which sets forth a restriction requirement in the above-captioned patent application.

Applicants first note that there appears to be some inconsistency between the restriction requirement and claims identified therein. To clarify, the claimed invention is directed to methods of (i) first screening test compounds to identify modulating agents which modulate a NF-AT-modulatory polypeptide (selected from Table 1), and (ii) then further examining the identified modulating agents for ability to modulate a NF-AT bioactivity. In the first step, test compounds can be screened for ability to modulate either the cellular level or other biological activities of the NF-AT-modulatory polypeptide. In the second step, the identified modulating agents can be further examined for ability to modulate either NF-AT activity in regulating expression of a NF-AT responsive gene or NF-AT's own expression level. The restriction requirement set forth in the Office Action appears to be directed to the second step. As such, Claim 8 should also be a linking claim since relative to claim 1 from which it depends, it recites an additional claim limitation that is directed to the first step, i.e., screening for compounds which modulate cellular level of the NF-AT-modulatory polypeptide (as opposed to expression level of NF-AT itself in the second step).

Subject to the above, Applicants elect **Group I**, which claims are drawn to methods of identifying an agent that modulates expression of an NF-AT-responsive gene.

The restriction requirement also includes a species election requirement under which Applicant is required to elect a single nucleotide species listed in Table 1. Applicants hereby elect the claims directed to methods of employing TRPV6 (Accession No. BC016101; molecule No. 7 in Table 1) to identify agents that modulate NF-AT ability in regulating expression of an NF-AT responsive gene. Claims 1, 2, 8-13, 15, 23 and 24 encompass the elected invention.

This election is made with traverse, as the restriction requirement improperly splits a single claim into multiple groups. Such a restriction requirement is improper as a matter of law. The courts have long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority to impose a rejection on a single claim, even if the claim presents multiple independently patentable inventions. *See, In re Weber*, 198 USPQ 328, 331 (CCPA 1978); *In re Haas*, 179 USPQ 623, 624-625 (*In re Haas I*) (CCPA 1973) and *In re Haas* 198 USPQ 334-337 (*In re Haas II*) (CCPA 1978).

In view of the foregoing, Applicants submit that the subject patent application is now in condition for substantive examination. If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-812-1547.

Respectfully submitted,

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Reg. No. 35,367

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